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<b>(21) International Application Number:</b> PCT/US99/02970 <b>(22) International Filing Date:</b> 12 February 1999 (12.02.99) <b>(30) Priority Data:</b> 60/075,002 17 February 1998 (17.02.98) US 60/093,128 16 July 1998 (16.07.98) US <b>(71) Applicant (for all designated States except US):</b> SOUTHERN RESEARCH INSTITUTE [US/US]; P.O. Box 55305, Birmingham, AL 35255-5305 (US). <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> DEAN, Alan, Hoyt [US/US]; 4401 Little River Road, Birmingham, AL 35213 (US). JOHNSON, David, Wayne [US/US]; 204 Inverness Cliffs, Birmingham, AL 35242 (US). HANNAH, Sidney, Joel [US/US]; Building 2, Suite 112, 9238 Highway 20 West, Madison, AL 35758 (US). <b>(74) Agents:</b> FLOAM, D., Andrew et al.; Needle & Rosenberg, P.C., 127 Peachtree Street, N.E., Atlanta, GA 30303 (US).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>Without international search report and to be republished upon receipt of that report.</i>
<b>(54) Title:</b> PATIENT DATA ACQUISITION UNIT AND DATA SUPPORT SYSTEM  <b>(57) Abstract</b>  A system for collecting patient data from patients featuring at least one mobile computing device, such as personal digital assistant (PDA) unit, that stores data representing predetermined medical forms to be populated with information collected from patients via the personal digital assistant (PDA) unit and at least one supporting application server. The PDA unit stores a software program to be executed by the processor to facilitate patient data entry in accordance with a predetermined medical form. The PDA unit is capable of connecting to a supporting application server via modem or through direct connection or indirectly through a computer network. The application server maintains and organizes scheduling information for both patients and their assigned healthcare professionals, contains data representing predetermined medical forms to be populated with patient health status information obtained via the personal digital assistant unit, and receives, formats, and preserves the data for export and use by other data processing systems.		

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## **PATIENT DATA ACQUISITION UNIT AND DATA SUPPORT SYSTEM**

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### **RELATED APPLICATION**

This application claims priority to U.S. Provisional Application No. 60/075,002, filed February 17, 1998, entitled "Data Collection Unit for Medical Practitioners" and to U.S. Provisional Application No. 60/093,128 filed July 16, 1998, entitled "Patient Data Acquisition and Support System for Nurses."

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### **FIELD OF THE INVENTION**

The present invention is directed to the collection of patient data, and more particularly to a patient data acquisition unit and data support system.

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### **BACKGROUND OF THE INVENTION**

There is an ever increasing need to automate the collection of patient data in the health care industry. This is true whether the data is collected from patients in hospitals or patients under home health care. Home health care, however, is a growing industry where automation has not occurred as rapidly as needed.

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Services being provided in the patients' home range from monitoring patient conditions during recovery from hospital care to continuous monitoring by an in-home nurse or aide. Patient data collection is necessary to monitor long term trends in patient status as well as to facilitate the practice of physicians and nursing staff. It is also useful for billing purposes.

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Up until recently, all data collection has been accomplished through the use of paper medical forms which are manually filled out during or after the visit by the visiting nurse or aide. There has been an effort made to improve the accuracy and legibility of the patient data. Personal laptop computers are being considered as a data collection tool. However, personal laptop computers are still fairly expensive and too large for light and portable applications. In addition, many patients find them intimidating and obtrusive.

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What is needed is a system by which a small inexpensive electronic data collection tool can be used in the field to help automate data collection of patient status.

## SUMMARY OF THE INVENTION

Briefly, the present invention is directed to a system for collecting health data from patients. The system comprises mobile computing devices which can be connected to one or more supporting computing devices to achieve the exchange of information between them. In its simplest configuration, the system consists of at least one personal digital assistant (PDA) unit that interfaces with at least one application server processor. The PDA is a mobile processor containing a program for acquiring data from patients using a suite of sensors, audible input, and/or manual input. The application server is used to transmit visit schedules to the PDA, recover patient data from the PDA following visits, and to store patient health data obtained from the PDAs. This minimum system will usually be expanded by adding additional database and communication servers in a networked architecture to support a plurality of PDAs.

The PDA unit comprises a processor and a memory and stores a software program which is executed by the processor to facilitate patient data entry in accordance with a predetermined medical form. The PDA unit is capable of connecting to the application server via direct connection or through a modem. The application server transmits data representing the predetermined medical forms to the PDA unit and receives from the PDA unit data representing populated medical forms. These data are typically processed further in preparation for their transmission to a larger patient records database.

In addition, the present invention is directed to the combination of a PDA and a sensor interface that connects with one or more patient data sensors for collecting health status information from the patient and automatically populating the medical forms in the personal digital assistant with the acquired data.

Other objects and advantages of the present invention will become more readily apparent when reference is made to the following description taken in conjunction with the accompanying drawings.

### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a block diagram of a system for collecting patient data according to the present invention.

5        Figure 2 is a block diagram of a personal digital assistant unit and a sensor interface according to one embodiment of the present invention.

Figure 3 is a block diagram of one embodiment the sensor interface.

Figure 4 is a flow chart showing the general operation of the system according to the present invention.

10       Figure 5 is a flow chart showing the method by which patient data information is collected by a personal digital assistant unit according to the present invention.

Figures 6-15 are sample screens displayed on the personal digital assistant unit to prompt attending personnel to enter data to be populated into a medical form.

### 15       DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Referring first to Figure 1, the patient data acquisition or collection system according to the present invention is shown generally at reference numeral 10. The system 10 comprises one or more mobile computing devices, such as personal digital assistants (PDAs) 20, and an application server 30. Connection of the application  
20       server 30 through a network 60 with other computer resources such as a communication server 50 and/or a database server 80 are typical approaches to expanding the system to handle a larger number of patients. The functions of the application server 30 and the database server 80 may reside in the same physical machine, or they may be distributed (as shown in Figure 1) as appropriate to the  
25       processing load anticipated for the system 10. The database server 80 organizes and maintains the collected patient medical information.

The PDA 20 is a well known piece of hardware that is capable of performing a variety of tasks. For example, the PDA 20 is PalmPilot™ PDA sold by 3Com Corporation, or a MobilePro™ PDA, sold by NEC. The PDA 20 receives software  
30       application functionalities from the application server 30. Other similar mobile computing devices are also suitable for use in accordance with the present invention.

Depending on the make and model of the PDA 20, it interfaces with the application server 30 through a cradle interface 40, by telephonic connection via an internal or external modem (not shown) over a telephone network 70, or via a standard serial interface cable (not shown). These interfaces are well known in the art and therefore are not shown or described herein. The software applications that manage the downloading of new applications or new data to the PDA 20 reside in application server 30. As is known in the art, new software applications or new data are installed in the PDA 20 when the PDA 20 is connected to the application server 30 and a "synchronization" operation is initiated. Similarly, data collected and stored in the PDA 20 are downloaded to the application server 30 during a "synchronization" operation. Some PDAs 20 have the capability to support certain downloading functions whereby only specific data can be designated for exchange between the PDA 20 and the application server 30.

Some PDAs 20 have built in keyboards, while others, such as the PalmPilot™ PDA have a graphical user interface which includes handwriting or speech recognition software to facilitate manual or voice data entry, respectfully. In addition, the PDA 20 has a display (not shown) that can present information in black-white or color. Text may be entered by writing directly onto a digitizer tablet that overlies the display or which may be separate from it. In accordance with the present invention, the functionality of the PDA 20 is refocused from its use as a personal contact manager/scheduler to the specific needs of the health care industry.

The application server 30 is a computer that stores (in an internal memory or hard disk) data representing one or more predetermined medical forms to be populated with information from a plurality of patients. These forms may be changed from time-to-time. For example, a typical medical form may be one of the Outcome and Assessment Information Set (OASIS) forms or what is commonly referred to as Nurses Notes, from a patient visit. Information that is collected by the one or more PDAs 20 is ultimately stored in one or more databases which themselves, may reside on other dedicated computers.

The network 60 may be any standard computer network known in the art, such as an Ethernet™ network for use internally by a hospital or home health care business.

Moreover, the network 60 could encompass data networks external to business, such as the Internet/World Wide Web.

Turning to Figure 2, a PDA 20 is shown together with a sensor interface/signal processor device 100 according to an alternative embodiment of the present invention. The sensor interface 100 connects to one or more patient data sensors 110 attached in, on or about the patient. Examples of sensors to which the sensor interface attaches are a temperature sensor, pulse/blood pressure sensor, blood glucose sensor, electronic scale, respiration monitor, etc. It is envisioned that as technologies develop, the sensor interface 100 may read data from microscopic in-body sensors in which a variety of medical information is derived from very small samples of a patient's biological fluids or tissues, or indirectly from other physical phenomena associated with the patient's body. The sensor interface 100 affords the ability to automatically read patient data sensors rather than requiring that the data be manually entered into the PDA 20.

An electrical block diagram for the sensor interface 100 is shown in Figure 3. Generally, the sensor interface 100 includes the ability to convert an analog output signal from a sensor to a digital signal suitable for storage by the PDA 20. For example, typical temperature sensors and blood pressure/pulse sensors may provide an analog output signal, while other sensors may provide a digital output. For those sensors that generate an analog output, one or several analog signal processor circuits 120 are provided to condition the analog output. An analog-to-digital converter (ADC) 130 converts the conditioned analog output to a digital signal. A digital data processor 140 connected to the ADC 130 processes the digital signal(s) representing the analog sensor output and organizes the information into a suitable data packet to be uploaded into a host device from the PDA 20. The sensor interface 100 may be powered by the PDA 20, or by an internal battery power conditioning supply 150. The sensor interface 100 connects to the PDA 20 by a standard cable, such as an RS-232 digital serial interface cable. The sensor interface 100 connects to the sensors 110 either by hardwire connection or by a wireless link via antenna 112. If a wireless link is employed the sensor interface 100 and sensors 110 would include suitable transmission and reception circuitry 160.

Reference is now made to Figure 4, in conjunction with Figures 1-3, for a description of the operation of the PDA 20 and the patient data acquisition system 10 in general. In Figure 4, the application server 30 is referred to as the "MediFORM Application Processor." In step 300, patient schedules are entered into the application server 30 either manually or through a network accessible external computer that contains and updates patient schedule information. Next, in step 310, the application server 30 allocates attending personnel (nurses, nurse/aides, doctors, etc.) in accordance with the patient visitation schedule. Then, in step 320, the data representing the medical form(s) is downloaded from the application server 30 to PDAs 20 via the cradle interface 40, telephone network 70, etc. Typically, these data are used to generate one or more forms which are presented on the PDA 20 display to guide the user through the data collection process.

In step 330, the user of the PDA 20 enters the data (either manually, electronically or audibly) into the PDA 20 at the patient site. This process will be described in greater detail hereinafter in conjunction with Figure 5. The information that is downloaded to a PDA 20 may include instructions for the nurse or aide to collect data from a plurality of specified patients.

Once all of the data from a patient or patients are collected, in step 340, the PDA is coupled to the application server 30 to upload data representing the populated medical forms. Alternatively, the data may be uploaded via telephone network 70. The data are uploaded from the PDA 20 to the application server 30 where it is processed in step 350 and formatted for storage in a database. The processing described in this step may be as simple as converging data from several reports into a permanent patient record or may involve the conversion from one database format to another in order to interface with the existing databases of a healthcare provider.

Finally, in step 360 the data, now properly formatted representing the populated medical forms, are transferred to the database server 80 for storage.

Turning now to Figure 5, the manner in which the patient data are collected and entered into the PDA 20 (step 330 of Figure 4) will be described. If the PDA 20 supports only manual data entry in step 332, then in step 334, the user enters data into the PDA through standard PDA user interfaces (keyboard, handwriting or speech recognition, etc.). On the other hand, if the PDA 20 is augmented to support



electronic and automatic data collection and entry via sensor interface 100, then in step 336, the sensor interface 100 is connected to the patient data sensors 110. Then, by initiating a procedure on the PDA 20, the sensor interface 100 triggers activation of the various patient sensors (if necessary) to obtain a reading of the related information, such as blood pressure/pulse rate, temperature, etc. Once the patient data sensors 110 make the information available, the sensor interface 100 reads the information from them, converts and/or processes the information as appropriate and uploads the information to the PDA 20. The PDA 20 receives the information and automatically populates the medical form for the patient.

Reference is now made to Figures 6-15 in which examples of the screens displayed on a typical PDA 20 are shown. Each screen includes icons or graphical button elements that can be selected by the user (with a stylus or some other means) to move to another screen containing additional information or data entry prompts.

Figure 6 illustrates an initial screen having two buttons: VISIT REPORT and VITAL STATISTICS. When the VISIT REPORT button is selected, the screen shown in Figure 7 is displayed. The screen in Figure 7 includes prompts to enter basic information about the particular patient and patient site being visited. This information is self explanatory. When all of this information is entered, the user selects the DONE button.

When the VITAL STATISTICS button is selected, the screen shown in Figure 8 is displayed. The VITAL STATISTICS screen includes data entry prompts for entering temperature, pulse rate, respiration, blood pressure, weight, and last bowel movement. All of this information may be entered manually, or as explained above, it may be entered electronically via the sensor interface 100. Another set of screens may be displayed to enter a variety of patient care information. These screens are shown in Figures 9-14, and are self-explanatory. The screens shown in Figures 9-14 are exemplary and in no way limit the expansion of these concepts to include other patient related information.

The last screen shown in Figure 15 is a general entry screen where general comments can be entered by the attending personnel into the PDA 20 using the PDA's text and speech recognition capabilities.

In summary, the present invention is directed to a method of acquiring health data from patients comprising steps of: generating information representing a medical form to be populated with patient data collected from a plurality of patients; storing the information representing the medical form in a mobile computing device, such as portable digital assistant (PDA) unit; collecting patient health data from patients, inputting the patient health data into the PDA, and populating a medical form in the PDA unit with patient health data collected for each patient; and uploading data representing populated medical forms from the PDA unit to a database for storage therein. The information representing the medical form may initially reside on an application server, and the PDA unit receives the information over a communication network during a "synchronization" procedure or other dedicated downloading procedure.

Similarly, the present invention is directed to a system for collecting patient data from patients, comprising: a network supporting communication and exchange of information between devices connected thereto; an application server connected to the network that stores data representing a predetermined medical form to be populated with information collected from patients and for storage in a database; and at least one mobile computing device, such as a personal digital assistant (PDA) unit, comprising a processor and a memory, the memory of the PDA unit storing a software program and information representing the predetermined medical form received from the application server, the processor of the PDA unit executing the software program to populate the predetermined medical form with patient health data received as input to the PDA unit.

Finally, the present invention also is directed to the combination of a mobile computing device, such as a personal digital assistant (PDA) unit, and a sensor interface. The PDA unit comprises a processor and a memory, the memory of the PDA unit storing a software program and information representing a predetermined medical form received from the application server, the processor of the PDA unit executing the software program to populate the predetermined medical form with patient health data received as input to the PDA unit. The sensor interface receives the patient health data from one or more sensors attached to, implanted in or which otherwise derive information from the patient's body, wherein the PDA unit receives

the patient health data from the sensor interface and automatically populates the medical form in the PDA unit with the patient health data.

The foregoing description is intended by way of example only and is not intended to limit the present invention in any way except as set forth in the following claims.

What is claimed is:

1. A system for collecting patient data from patients, comprising:  
a network supporting communication and exchange of information between devices connected thereto;  
an application server connected to the network that stores data representing a predetermined medical form to be populated with information collected from patients and for storage in a database; and  
at least one mobile computing device comprising a processor and a memory, the memory of the mobile computing device storing a software program and information representing the predetermined medical form received from the application server, the processor of the mobile computing device executing the software program to populate the predetermined medical form with patient health data received as input to the mobile computing device.
2. The system of claim 1, and further comprising a sensor interface that electrically connects to one or more patient data sensors for collecting patient data from the patient data sensors and automatically populating the medical forms in the mobile computing device with patient data sensor information.
3. The system of claim 1, and further comprising a database server connected to the network that supports and maintains the database of collected information.
4. The system of claim 1, wherein the mobile computing device is a personal digital assistant (PDA) unit.
5. A method for acquiring health data from patients comprising steps of:  
generating information representing a medical form to be populated with patient data collected from a plurality of patients;  
storing the information representing the medical form in a processor server;

downloading the information representing the medical form to a portable digital assistant mobile computing device;

collecting patient health data from patients, inputting the patient health data into the mobile computing device, and populating a medical form in the mobile computing device with patient health data collected for each patient; and

uploading data representing populated medical forms from the mobile computing device to a database for storage therein.

6. The method of claim 5, wherein the step of collecting patient data comprises manually or audibly entering patient data observed by an attending personnel into the mobile computing device.

7. The method of claim 5, wherein the step of manually entering comprises displaying a plurality of screens each representing a subset of queries for types of patient data to be manually or audibly entered by the attending personnel.

8. The method of claim 5, wherein the step of collecting comprises connecting a sensor interface to the mobile computing device and to one or more patient data sensors, electronically reading the patient data sensors, uploading patient data sensor information into the mobile computing device.

9. The method of claim 8, and further comprising the step of automatically populating the medical form in the mobile computing device with data collected from the patient data sensors.

10. In combination, a mobile computing device comprising a processor and a memory, the memory of the mobile computing device storing a software program and information representing a predetermined medical form received from the application server, the processor of the mobile computing device executing the software program to populate the predetermined medical form with patient health data received as input to the mobile computing device, and a sensor interface that receives patient health data from one or more sensors attached to, implanted in or which

otherwise derive information from the patient's body, wherein the mobile computing device receives the patient health data from the sensor interface and automatically populates a medical form stored in the mobile computing device with the patient health data.

11. A method of acquiring health data from patients comprising steps of:
  - generating information representing a medical form to be populated with patient data collected from a plurality of patients;
  - storing the information representing the medical form in a portable digital assistant (PDA) unit;
  - collecting patient health data from patients, inputting the patient health data into the PDA, and populating a medical form in the PDA unit with patient health data collected for each patient; and
  - uploading data representing populated medical forms from the PDA unit to a database for storage therein.

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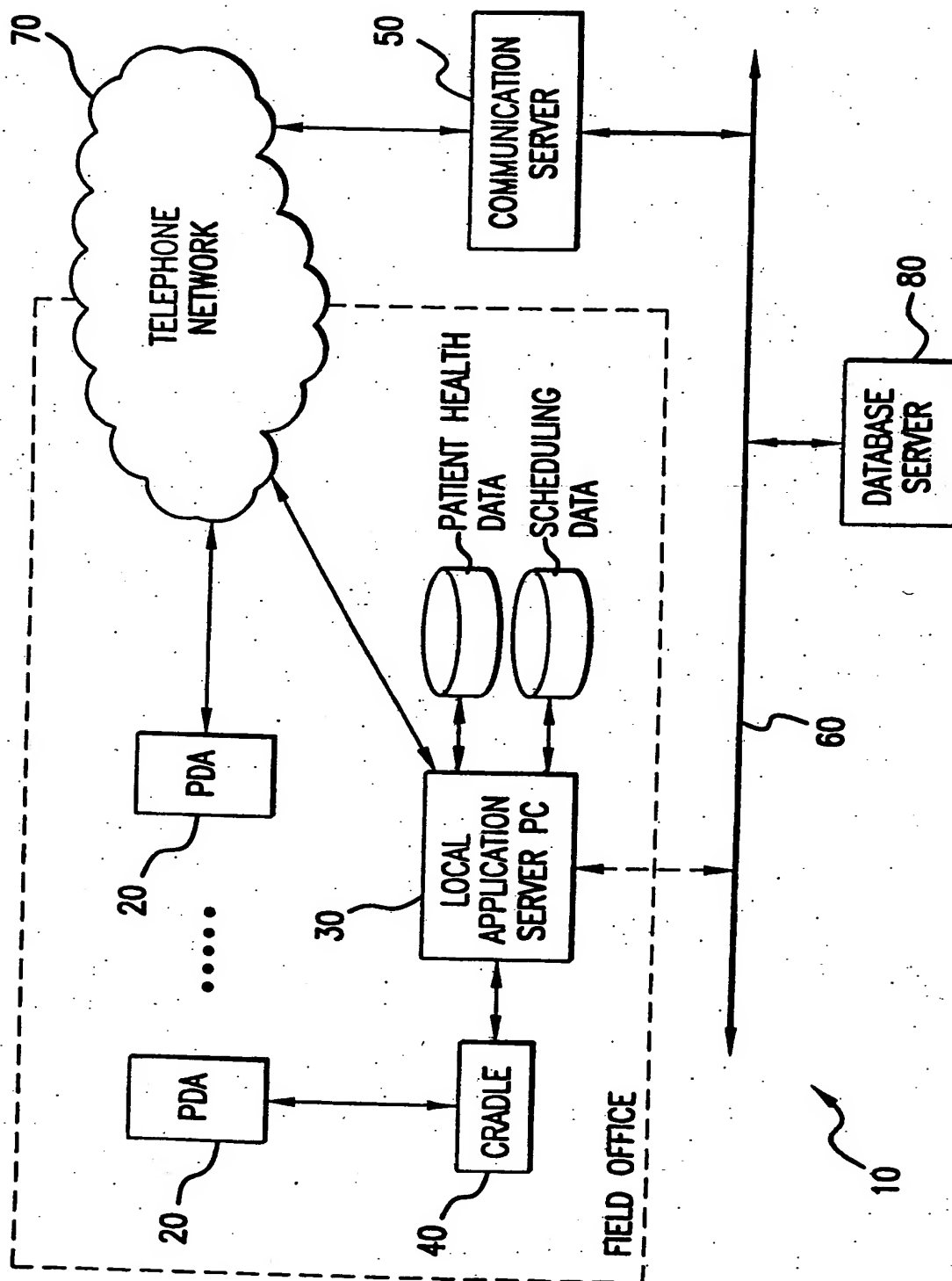


FIG.1

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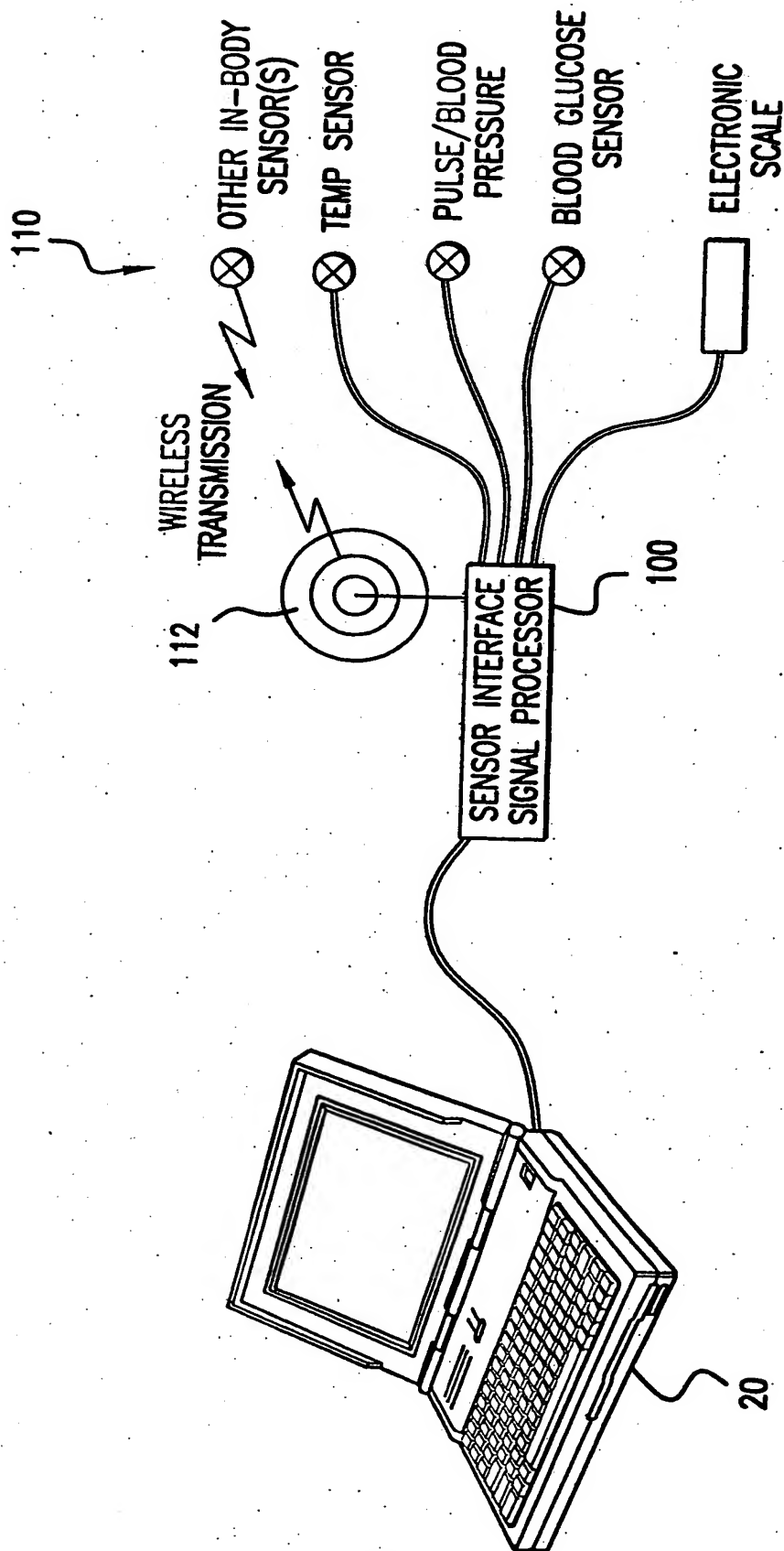


FIG. 2



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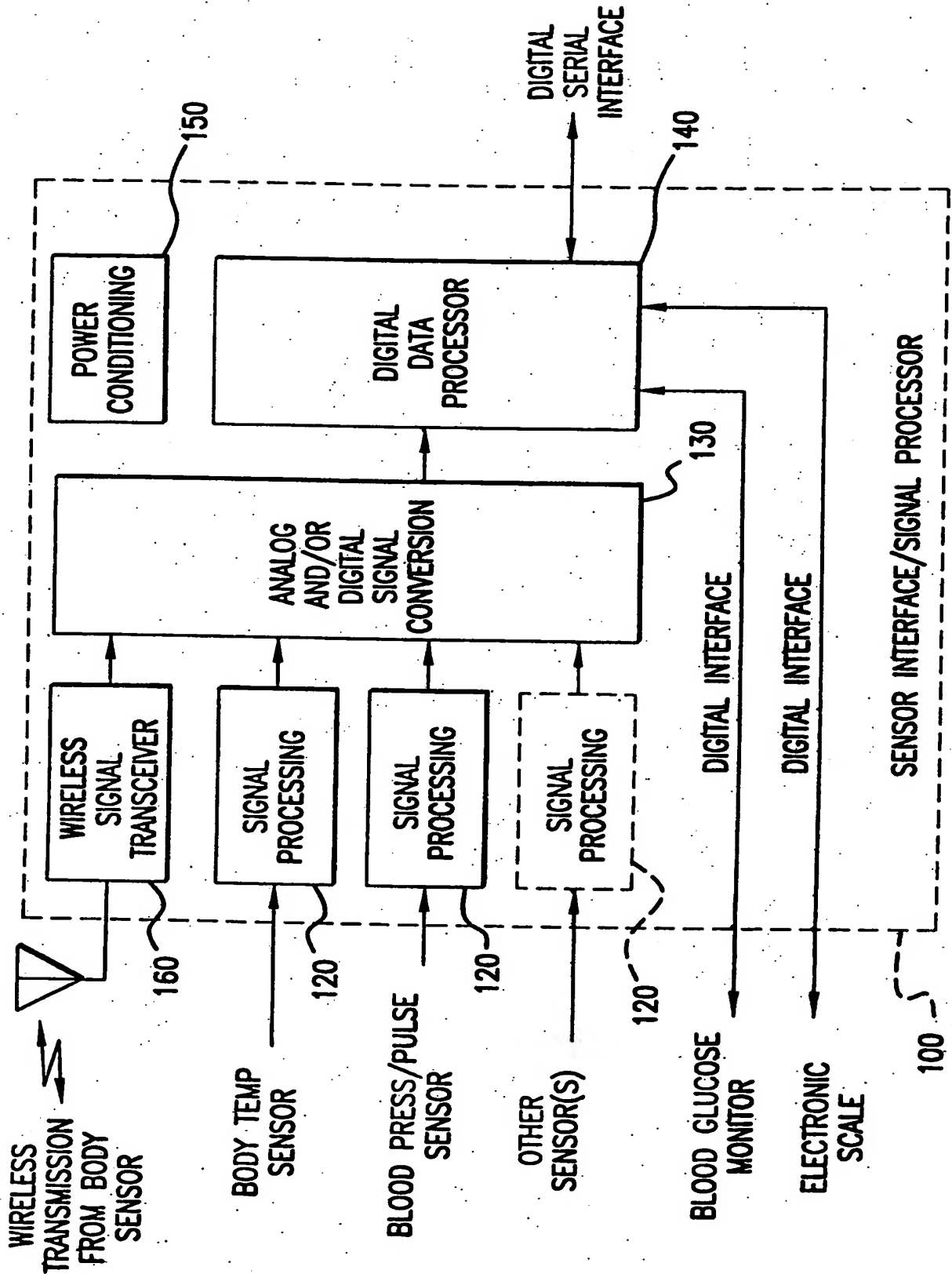


FIG. 3

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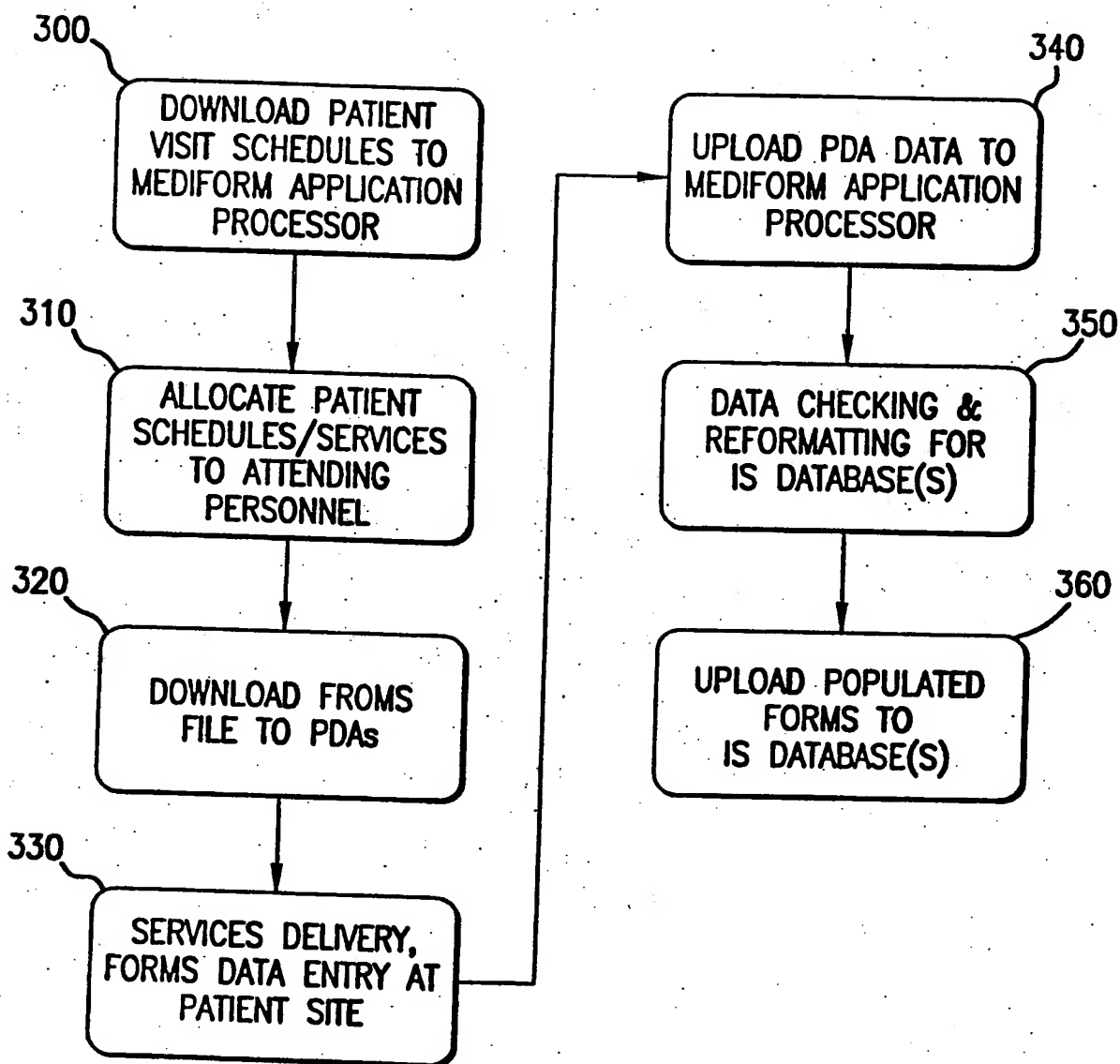


FIG.4

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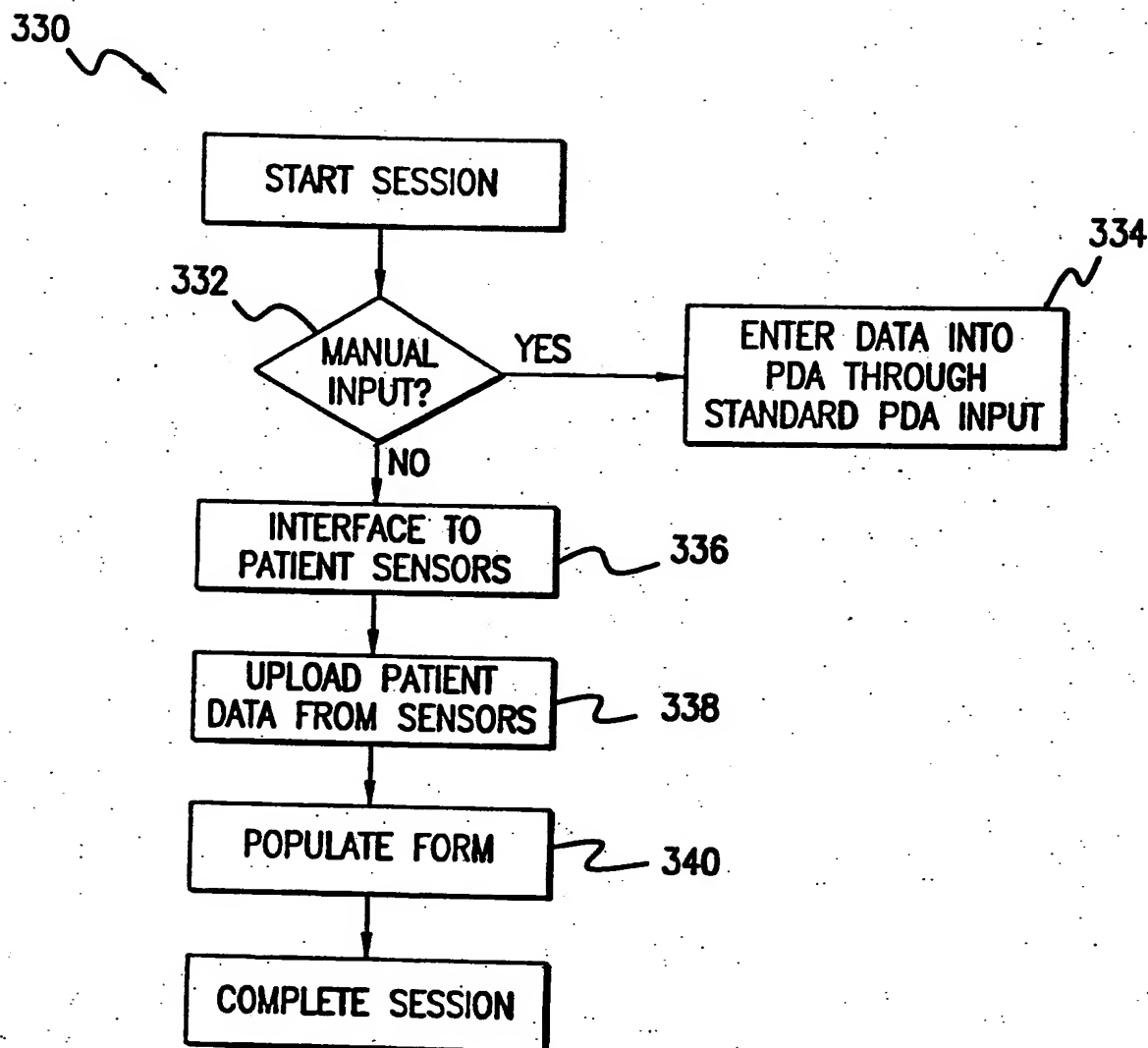


FIG.5

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MediFORM

VISIT REPORT

PATIENT NAME: ▽ WILLIAM BIXBY

MEDICAL RECORD# \_\_\_\_\_

VITAL STATISTICS

APPLICATION

MENU

obc

123

CALC

FIND

The screen displays a medical form interface. At the top, it says 'MediFORM'. Below that is a button labeled 'VISIT REPORT'. The form fields include 'PATIENT NAME: ▽ WILLIAM BIXBY' and 'MEDICAL RECORD# \_\_\_\_\_'. Below these is another button labeled 'VITAL STATISTICS'. The bottom section of the screen features a central display area with a cursor and the text 'obc' and '123'. To the left of the display are buttons for 'APPLICATION' and 'MENU'. To the right are buttons for 'CALC' and 'FIND'. At the very bottom, there are five circular navigation buttons.

FIG.6

VISIT REPORT

PATIENT NAME \_\_\_\_\_

VISIT CODE \_\_\_\_\_

SCHEDULE CODE \_\_\_\_\_

DESTINATION CODE \_\_\_\_\_

ODOMETER \_\_\_\_\_

ARRIVAL TIME \_\_\_\_\_

DEPARTURE TIME \_\_\_\_\_

DONE

APPLICATION

MENU

obc

123

CALC

FIND

This screen is similar to FIG.6 but with more input fields. It starts with a 'VISIT REPORT' button. Below it are seven input fields: 'PATIENT NAME', 'VISIT CODE', 'SCHEDULE CODE', 'DESTINATION CODE', 'ODOMETER', 'ARRIVAL TIME', and 'DEPARTURE TIME'. A 'DONE' button is located below the input fields. The bottom section of the screen features a central display area with a cursor and the text 'obc' and '123'. To the left of the display are buttons for 'APPLICATION' and 'MENU'. To the right are buttons for 'CALC' and 'FIND'. At the very bottom, there are five circular navigation buttons.

FIG.7

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A screenshot of a handheld device screen titled "VITAL STATISTICS". The screen lists several vital signs with corresponding input lines: TEMP, PULSE, RESPIRATION, BLOOD PRESSURE, BLOOD GLUCOSE, WEIGHT, and LAST BM. Below the list are two buttons: "UPLOAD SENSORS" and "DONE". At the bottom of the screen is a navigation bar with five circular icons: a left arrow, a right arrow, a double horizontal bar, and two more circular icons. The screen also features a central display area with a graph showing a peak and the text "abc" and "123". To the left of the graph is an "APPLICATION" button with a circular icon, and below it is a "MENU" button. To the right of the graph are "CALC" and "FIND" buttons, each with a circular icon.

FIG. 8

A screenshot of a handheld device screen titled "PATIENT CARE". The screen displays a list of bath types with checkboxes: "BED COMPLETE", "BED PARTIAL", "CHAIR COMPLETE", "CHAIR PARTIAL", "TUB", and "SHOWER". Below the list is a navigation bar with five circular icons: a left arrow, a right arrow, a double horizontal bar, and two more circular icons. The screen also features a central display area with a graph showing a peak and the text "abc" and "123". To the left of the graph is an "APPLICATION" button with a circular icon, and below it is a "MENU" button. To the right of the graph are "CALC" and "FIND" buttons, each with a circular icon.

FIG. 9

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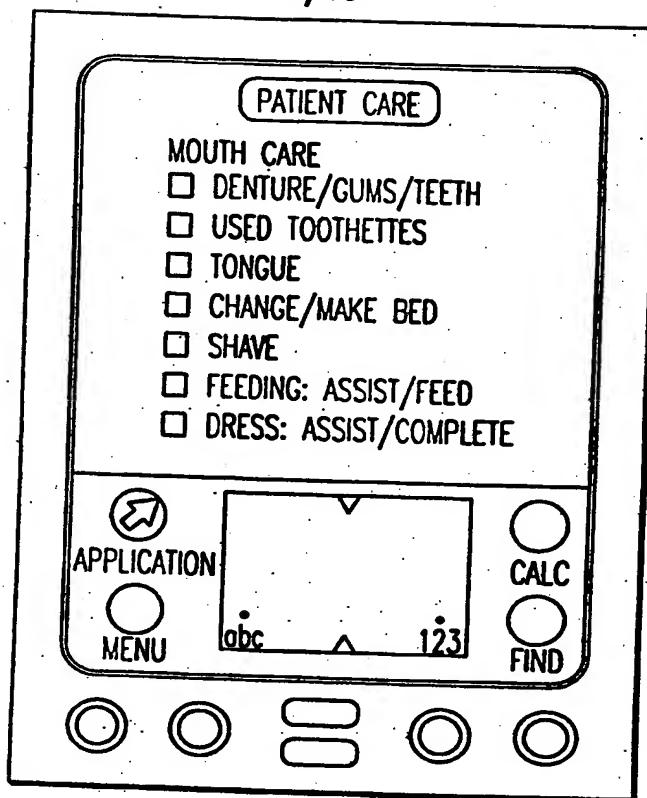


FIG. 10

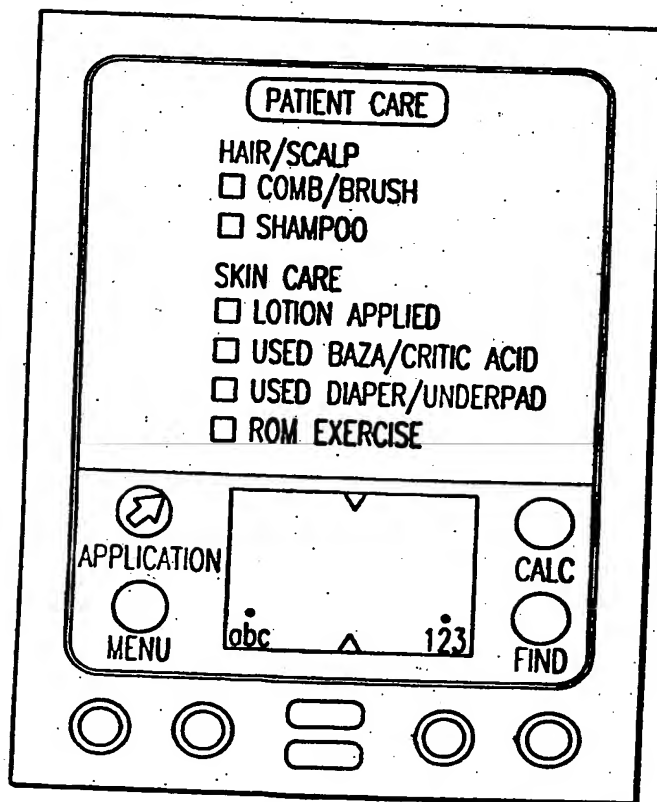


FIG. 11

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PATIENT CARE

NAIL CARE

- ☐ CLEANED
- ☐ TRIMMED
- ☐ FILED

ENEMA

- ☐ FLEET
- ☐ WATER
- ☐ PERINEAL

APPLICATION MENU

123

CALC FIND

FIG. 12 is a schematic diagram of a patient care screen. It features a title bar 'PATIENT CARE' at the top. Below it are two sections: 'NAIL CARE' with three checkboxes for 'CLEANED', 'TRIMMED', and 'FILED'; and 'ENEMA' with three checkboxes for 'FLEET', 'WATER', and 'PERINEAL'. At the bottom, there is a control panel with a left section containing an 'APPLICATION' button with a star icon and a 'MENU' button; a central display area showing '123' and 'abc'; and a right section with 'CALC' and 'FIND' buttons. Below the control panel are five circular buttons and a central rectangular button.

FIG. 12

PATIENT CARE

CATHETER CARE

URINE OUTPUT: \_\_\_\_\_

- ☐ ASSIST WITH AMBULATION
- ☐ TRANSFER TO BED/CHAIR
- ☐ USE OF TRANSFER BELT
- ☐ TIDY PATIENT ROOM

APPLICATION MENU

123

CALC FIND

FIG. 13 is a schematic diagram of a patient care screen. It features a title bar 'PATIENT CARE' at the top. Below it are two sections: 'CATHETER CARE' with a 'URINE OUTPUT' field followed by a line, and a list of four checkboxes: 'ASSIST WITH AMBULATION', 'TRANSFER TO BED/CHAIR', 'USE OF TRANSFER BELT', and 'TIDY PATIENT ROOM'. At the bottom, there is a control panel with a left section containing an 'APPLICATION' button with a star icon and a 'MENU' button; a central display area showing '123' and 'abc'; and a right section with 'CALC' and 'FIND' buttons. Below the control panel are five circular buttons and a central rectangular button.

FIG. 13

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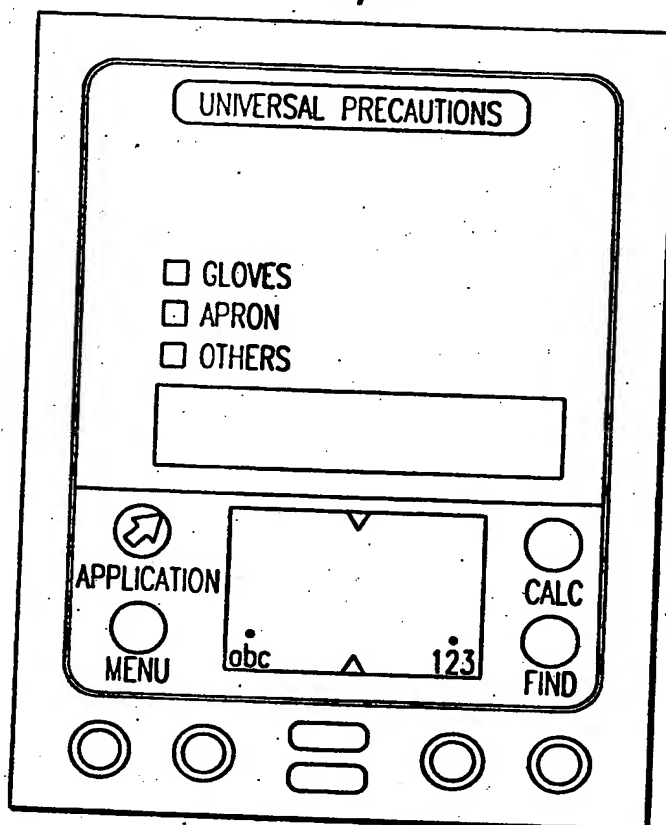


FIG. 14

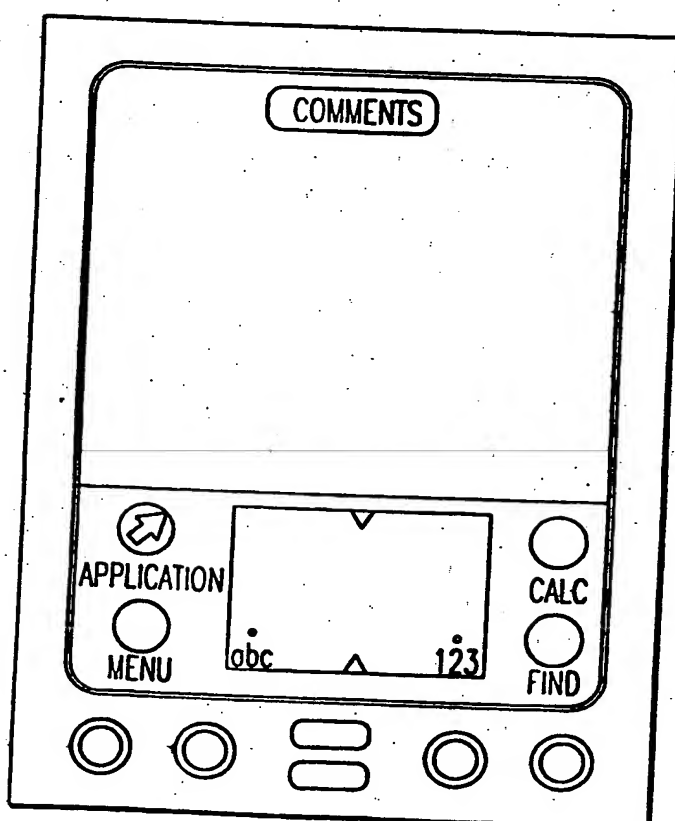


FIG. 15